HDMA
Healthcare Distribution
Management Association
Products, Services and Information for Your Health

Jon Borschow, Chairman of the Board
Ronald J. Streck, President & CEO

April 2, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; [Docket No. 02N-0276; 68 FR 5378; February 3, 2003; RIN 0910-AC40]

Dear Sir or Madam:

Please find attached the original and two hard copies of the public comments by the Healthcare Distribution Management Association (HDMA) regarding this proposed regulation. These copies are exact duplicates of the version electronically submitted by our organization to you earlier today.

If you have any questions, please do not hesitate to contact me at 703/787-0000 ext. 240 or aducca@hdmanet.org. Thank you.

Sincerely,

Anita T. Ducca

Anita T. Ducca
Director, Regulatory Affairs

Enclosures

02N-0276 C134

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RE: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; [Docket No. 02N-0276; 68 FR 5378; February 3, 2003; RIN 0910-AC40]

Dear Sir or Madam:

The Healthcare Distribution Management Association (HDMA) is the national trade association representing pharmaceutical and related healthcare product distributors. HDMA active member companies operate over 230 distribution centers throughout the country that serve every state, the District of Columbia, and U.S. territories. On behalf of our 77 member companies, we would like to submit comments on the Department's February 3, 2003, proposed rule (68 FR 5378) to establish the process for registration of food facilities as required under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188 Sec. 415).

HDMA member companies' operations span a vast array of distribution of healthcare related products. While the largest part of the business is distribution of pharmaceutical products to pharmacies and healthcare providers, many of our members also provide value-added services that include stocking over-the-counter drugs and assorted healthcare sundries. Included in this miscellaneous limited inventory of products are items that fall under the definition of food as cited in 21 CFR 170.3(n) and 21 CFR 170.3 (o), such as (n25) cough drops, (n31) weight control milk beverages, and (o20) nutrient supplements (vitamins).

HDMA commends the Agency for incorporating comments received from stakeholders prior to the release of this proposed rule that will ease the burden on those required to register. Specifically, HDMA agrees that registration should be a one-time, no fee process and that there should be an electronic system established for registration.

HDMA distributor members are heavily regulated and registered with various government agencies. All distribution centers that distribute pharmaceuticals are licensed with the state licensing agency as required under the Federal Prescription Drug Marketing Act [PDMA (PL 100-293)] and in addition, if they distribute controlled substances they are registered with the Drug Enforcement Administration under the Controlled Substances Act [CSA (PL 91-513)].

Both laws require storage and handling security procedures to protect the products from diversion and theft.

HDMA Comments:

General Provisions

Under *§1.227 What definitions apply to this subpart?*, facility is defined as "any establishment, structure or structures under one management at one general physical location."

Due to the limited amount of products that each healthcare product distribution facility may carry that would fall under the food definition [21 CFR 170.3(n) and 21 CFR 170.3 (o)] and the fact that each distribution facility is registered to handle pharmaceutical products under the PDMA, we would recommend that the registration process be flexible to allow a company to decide whether to provide a corporate registration of all facilities held under the company name or individual registration of each facility based on the type of inventory held at the specific site.

Conclusion

On behalf of HDMA, and all of our healthcare product distributor members, we appreciate this opportunity to comment and share our industry's perspective on this proposed rule. HDMA and its members take the threat of a bioterrorism attack very seriously and have worked closely with the Centers for Disease Control, Department of Homeland Security, FDA and other emergency government agencies to determine ways our members can provide assistance in the event of a national crisis.

If HDMA may be of assistance to you on this or any other matter, please do not hesitate to contact me at 703/787-0000 ext. 240 or aducca@hdmanet.org.

Sincerely,

Anita T. Ducca

Anita T. Ducca
Director, Regulatory Affairs